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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/621,272	07/17/2003	Olivier Poterat	I/1368	3309
28501	7590	08/11/2005	EXAMINER	
MICHAEL P. MORRIS BOEHRINGER INGELHEIM CORPORATION 900 RIDGEBURY ROAD P. O. BOX 368 RIDGEFIELD, CT 06877-0368			GUDIBANDE, SATYANARAYAN R	
			ART UNIT	PAPER NUMBER
			1654	

DATE MAILED: 08/11/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/621,272

Applicant(s)

POTTERAT ET AL.

Examiner

Satyanarayana R. Gudibande

Art Unit

1654

— The MAILING DATE of this communication appears on the cover sheet with the correspondence address —

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) 4-6,8,13-15 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) 1-15 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☒ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: ____.

DETAILED ACTION

Election/Restrictions

Applicant's election of single species as disclosed in claim 10 (currently amended) in the reply filed on June 22, 2005 is acknowledged. Further, it is also acknowledged that the claim 16 has been canceled, claim 17 has been withdrawn pending Examiner's action and amendment to claim 2 has also been noted.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3, 7, 9, 11 and 12, are rejected under 35 U.S.C. 102(b) as being anticipated by US 6,211,145 (issued to Yanai, et al.).

Claims 4-6, 8, and 13-15 are withdrawn from consideration. Because, the specific compound disclosed in prior art does not read on these claims. Under election of species practice in Markush-type claim, following election, the Markush-type claim will be examined fully with respect to the elected species and further to the extent necessary to determine patentability. If the Markush-type claim is not allowable over the prior art, examination will be limited to the Markush-type claim and claims to the elected species, with claims drawn to species patentably distinct from the elected species held withdrawn from further consideration (see MPEP 803.02).

Applicants claim a bicyclic oligopeptide having glucagons inhibitor activity wherein, the first cyclic group comprised of an amide bond between a cysteine and a second carboxylate

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group of a diacid amino acid, a second cyclic group formed via a disulfide bond between the α -carboxylate group of the said diacid and a C-terminal cysteine and a cystine group within the first cyclic group.

Yanai, et al., teaches the invention of a bicyclic depsipeptide as depicted in Figure 1 below. In Figure 1, we have a cysteine moiety (a disulfide bond between the two-cysteine amino acids B and F) (letter G represents –S-S- bond). Moiety 'W' could be the diacid amino acid that forms the first cyclic ring via an amide bond using the second carboxylate group. It forms the second cyclic ring using the α -carboxylate group of 'A' a diacid via an amide group with the C-terminal cysteine of the first cyclic ring. 'W' can be Glu or Asp; 'D' can be Ala; 'Z' can be Asp or Glu; 'E' can be Val and 'A' can be Asp amino acid.

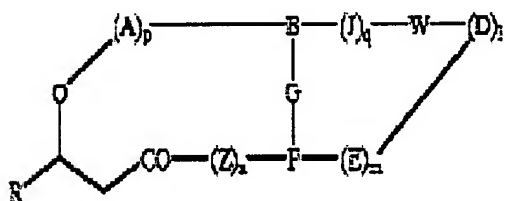


Figure 1

For the purpose of 101 and 112 issues and those issues alone, all of the claims have been examined to expedite prosecution. Inclusion of these claims in no way implies that these claims have been examined for prior art purposes. This application has been subjected to election of species. An appropriate art rejection on the appropriate claims has been made supra.

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35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-3 and 7-12 are rejected under 35 U.S.C. 101, because, the claimed invention is directed to non-statutory subject matter. In the present instance, the bicyclic peptide as recited in claim 1 of the invention, applicants do not provide a method of obtaining the peptide. However, as disclosed by the applicants in the specification (page 4, lines 3-6), the bicyclic peptide is present in *Streptomyces Sp.*, (Accession No. DSM 14996), and hence it is a product of nature. Therefore, Claims 1-3 and 7-12 are rejected under 35 U.S.C. 101.

Claims 4-6 and 13-15 are withdrawn from further consideration.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-9 and 11-15 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

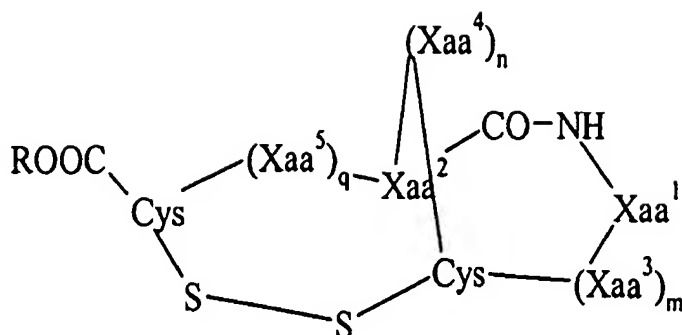


Figure 2

Applicants claim a bicyclic oligopeptide with a general formula as shown in Figure 2, having glucagon receptor inhibitor property. In the instant case, the general formula in figure 2 represents a myriad number of species. Applicants are not in possession of all species beyond the compounds disclosed in the specification. It should be further noted that *Streptomyces Sp.*, produces other mono, bi and tricyclic peptides that differ in structure and functions (Yano, et al., 1996, Bioorganic & Medicinal Chemistry, 4, 115-120; Renner, et al., 1999, J. Am. Chem. Soc., 121, 11273-76 and He, et al., 1995, Bioorganic & Medicinal Chemistry, 5, 621-626). Hence, different molecules represented by different structural formulae derived from the general structural formula as shown in Figure 2, result in functionally different molecules. The examples in the specifications are confined to a single peptide that is obtained from a single variant of streptomyces. The Streptomyces variant disclosed by applicant is DSM 14996. The specification does not provide any written description of other streptomyces strains or bi-cyclic peptides, that fulfill the structural requirements of applicant's isolated and purified peptide. Written description can be fulfilled by disclosure of other species of bicyclic peptides having

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structure-function relationship similar to the claimed species to show that the applicants are in possession of the claimed genus. A generic statement of a bi-cyclic peptide that cyclized in the manner, as described and as recited in claim 1, does not provide sufficient evidence to the possession of the claimed genus of bicyclic peptides by applicants. Note that the prior art disclose other monocyclic, other bicyclic, and tricyclic peptides that have been isolated from different strains of streptomyces which are structurally distinct from the applicant's claimed peptide. Therefore, applicants neither disclose other species of bicyclic peptides that may be obtained from the source DSM 14996, nor other species of streptomyces organisms that produce bicyclic peptides with structure-function relationship similar to the claimed bicyclic peptide.

A second means of fulfilling written description requirement is the disclosure of a representative number of examples in the specification. A single embodiment does not constitute requisite representative number. Therefore, the claims 1, 7 and 8 lack written description because there is no correlation between the number of species claimed and actual number species that the applicants are in possession of, and the inherent unpredictability in functional characteristics that is expected from the structural nuances present in different molecules.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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Claim 10 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Examiner is unable to decipher meaning of the symbol represented by “ \lceil xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx \rceil ” in SEQ ID No. 1 (as shown in Figure 3) of claim 10 represents.

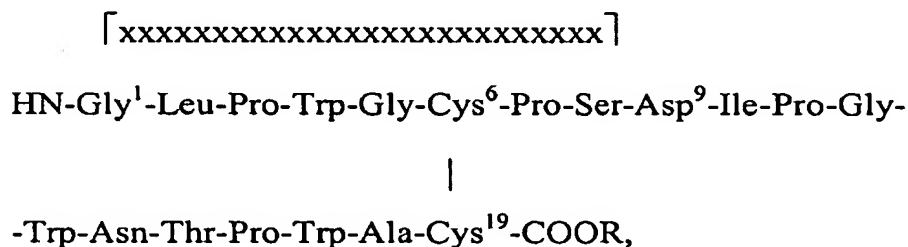


Figure 3.

Conclusion

ALL CLAIMS ARE REJECTED.

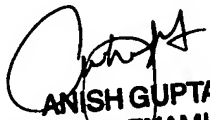
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Satyanarayana R. Gudibande whose telephone number is 571-272-8146. The examiner can normally be reached on M-F 8-4.30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

srg

 8/8/05
ANISH GUPTA
PRIMARY EXAMINER